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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,123	02/18/2004	Mark W. Kroll	A04P1016US01	5391
36802 7590 03/06/2007 PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EXAMINER BERTRAM, ERIC D	
			ART UNIT	PAPER NUMBER
			3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/782,123

Applicant(s)

KROLL, MARK W.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/8/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-20 and 22-25 have been considered but are moot in view of the new ground(s) of rejection. Furthermore, since the applicant did not traverse the examiner's assertion of Official Notice it is taken as admitted prior art that changes in heart rate variability is old and well known to those skilled in the art as a strong indicator of cardiac arrhythmia, specifically T-wave alternans. See 37 CFR 1.111(b).

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/8/2006 was filed in compliance with the provisions of 37 CFR 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The amendments to the specification received on 12/8/2006 are acknowledged and accepted. The objection to the specification has been withdrawn.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-20 and 22-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/782,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both describe methods and apparatuses for recording diagnostic data in an implantable device based on the detection of predetermined triggers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 5,908,392, hereinafter Wilson) in view of Legal Precedent. Wilson discloses a system and method for recording and storing medical data in response to a programmable trigger. Wilson describes that triggers may be modified and set by a medical practitioner in order to ensure that only necessary data is stored, as deemed by the practitioner (Col. 12, lines 50-61 and Col. 4, lines 10-15). Since the triggers are set by the practitioner, they are inherently chosen by evaluating the likelihood of important diagnostic data being associated with the predetermined triggers. Based on these predetermined triggers, the system will record data prior to, during and subsequent to important cardiac episodes that are being monitored by the system (Col. 4, lines 4-8). Wilson states that the data to be recorded can include IEGMs and event records (Col. 7, lines 40-65). Furthermore, the triggers can include fast beat threshold values between 90 and 200 bpm (Col. 9, lines 21-25) as well as and morphology thresholds, which in this case are consecutive premature ventricular contractions (PVC) or pacemaker-mediated tachycardia (PMT) (Col. 9, lines 30-45). Finally, Wilson discloses that the data is held in a temporary snapshot buffer prior to being moved and stored in permanent memory (Col. 9, line 54-Col. 10, line 22).

9. However, Wilson does not disclose that a processor in an implantable medical device (IMD) adaptively and automatically modifies the triggers. Attention is directed to

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In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (see MPEP 2144.04).

It has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. In this case, as admitted by the applicant in the remarks received 12/8/2006, Wilson discloses that some processes, including adaptively modifying recording triggers was done manually by a medical practitioner instead of automatically by a processor in an IMD. Therefore, it would have been obvious to one of ordinary skill in the art to provide automatic means such as a processor in the IMD of Wilson to replace the manual activity of adaptively modifying recording triggers as disclosed by Wilson based on the legal precedent set by *In re Venner*.

10. Regarding claims 7, 8 and 15-20, Wilson, as described above, discloses the applicant's basic invention with the exception of specifically disclosing the medical practitioner reviews the data in order to determine if the triggers were correctly set to record important diagnostic data. However, Wilson does disclose that the practitioner reviews the data recorded during follow-up visits in order to appraise the performance of the implantable device (Col. 4, lines 28-41). While it is not stated, one of ordinary skill would assume that if the data recorded was not found to be adequate, then the practitioner would adjust the recording triggers accordingly in order to capture the best data possible in the future. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method of Wilson by varying the triggers after appraisal of the implantable device in order to record the best

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and most prevalent data possible in order to provide the best care possible to the patient.

11. Regarding claims 16 and 17, Wilson discloses counting the number of consecutive beats that have PVC or PMT and when the occurrence is 1-15 consecutive times initiating recording of the data (Col. 9, lines 30-45).

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Legal Precedent and further in view of Official Notice. Wilson, as described above, discloses the applicant's basic invention with the exception of using heart rate variability changes as an indication of arrhythmia. However, the Examiner takes Official Notice that changes in heart rate variability is notoriously well known to those skilled in the art as a strong indicator of cardiac arrhythmia, specifically T-wave alternans. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Wilson to incorporate heart rate variability (HRV) as a trigger since it is well known in the art that HRV is an indicator of cardiac arrhythmia.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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